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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,746	10/20/2000	David E. Lowery	6297.1cp-PUJ-0295	7494

7590

07/29/2002

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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,746

Applicant(s)

LOWERY ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-45, 47-58 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 8
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group CCLXXXVIII, claims 46 and 59, in Paper No. 10, 6/14/2002 is acknowledged. The traversal is on the ground(s) that the claims are amenable to further grouping, and that such grouping would not impose a burden on the Examiner. This is not found persuasive because, the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05. A burden would be imposed on the Examiner to search extra groups, because each distinct Group requires a separate field of search, and a search of one Group would not reveal art on the other Groups, thus imposing a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-45, 47-58, 60-62 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 46 and 59 are under consideration.

Information Disclosure Statement

References FP-FZ on the IDS of Paper No. 4, filed 6/11/2001 have been lined through because fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of an item of information contained in an information disclosure statement or the submission of any missing element(s) is the date of submission for purposes of

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determining compliance with the requirements based on the time of filing the statement, including all certification requirements. See MPEP § 609 C(1-2).

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46 and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound capable of modulating binding between SEQ ID NO: 157 and SEQ ID NO: 22, does not reasonably provide enablement for a method for identifying a compound capable of modulating binding between a DmGPCR and a DmGPCR binding partner, or DmGPCR9 and SEQ ID NO: 157. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 46 and 59 are overly broad in the recitation of DmGPCR, DmGPCR9, and a DmGPCR binding partner. The specification discloses that the term DmGPCR embraces species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines 17-21), and allelic variants (page 19, lines 4-7). Insufficient guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic

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effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the terms DmGPCR, DmGPCR9 or DmGPCR binding partner encompasses species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines 17-21), and allelic variants (page 19, lines 4-7), and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to practice the claimed method. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to a method for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner.

(2) the nature of the invention - The instant invention is a method of compound identification.

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(3) the state of the prior art - The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrates the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught a method for identifying a compound capable of modulating binding between SEQ ID NO: 157 and SEQ ID NO: 22, not methods for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner.

(7) the existence of working examples - Working examples are not provided for methods for identifying a compound capable of modulating a species homologs, fragments of the full length polypeptide, and allelic variants of a DmGPCR, a DmGPCR9 or a DmGPCR binding partner.

(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 46 and 59 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

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Claims 46 and 59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. According to the specification, the term DmGPCR embraces species homologs (page 18, lines 19-27), fragments of the full length polypeptide (page 19, lines 17-21), and allelic variants (page 19, lines 4-7). The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 22 and SEQ ID NO: 157. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 157 and SEQ ID NO: 22 are insufficient to describe the genus.

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One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46 and 59 are vague and indefinite in the recitation of the terms "DmGPCR", and "DmGPCR9". There is no definition within the claim to define the protein to which these acronyms refer. Thus, the metes and bounds of this claim cannot be determined

The use of the term "represented" in claim 59 renders the claim vague and indefinite. It is not clear whether this term imposes an open or closed limitation on the sequence of the peptide as set forth in SEQ ID NO: 157, thus the metes and bounds of the claim cannot be determined.

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Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
July 24, 2002



DAVID S. ROMEO
PRIMARY EXAMINER